K012088

510(k) Summary – 21 CFR § 807.92(c)

Submitter's Name and Contact Information
Nastech Pharmaceutical Company, Inc (Nastech)
45 Adams Avenue
Hauppauge, NY 11788

DEC 1 8 2001

Contact Person
Peter C. Aprile, R.Ph.
Senior Director, Regulatory and Quality Affairs

Summary Preparation Date
17 May 2001

Device Names

Trade Name:	Mammary Aspiration Specimen Cytology Test (MASCT)
Common Name:	Breast Aspirator
Classification Name:	Gastroenterology-Urology Biopsy Instrument (21CFR § 876.1075)

Substantially Equivalent Device
Substantial equivalence was claimed to Windy Hill Technology DucPrep™ Breast Aspirator.

Device Description
The Nastech MASCT device is similar to similar to the non-powered breast pumps Manufactured by Windy Hill Technology used to elicit and collect nipple aspirate fluid (NAF) from the excretory ducts (tubuli lactiferi or galactophori). The device is comprised of a rigid polycarbonate cup in which the sample collection container is inserted. Negative pressure (vacuum) is produced by non-powered (hand) actuations of a lever like handle. The expressed NAF sample is collected on a membrane filter and washed into the sample container using an appropriate fixative solution.

Intended Use
The MASCT device is intended for use in the collection of nipple aspirate fluid for laboratory cytological testing.

Technological Characteristics
The MASCT is a device that is substantially equivalent to the non-powered breast pumps Manufactured by Windy Hill Technology used to elicit and collect nipple aspirate fluid from the excretory ducts (tubuli lactiferi or galactophori). The Nastech device shares similar design, material and operating characteristics as the Windy Hill Device and devices to which the Windy Hill device claims substantial equivalence. The subject device and predicate device are comprised of polymer cups that are placed over the breast nipple and are used in conjunction with a non-powered mechanism for applying a gentle vacuum enabling expression of nipple aspirate fluid.

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Data Supporting Substantial Equivalence

Nastech conducted in-vitro and clinical studies to verify and validate the device design. The results of that testing supported the conclusion that the MASCT device is safe and effective for its intended use. In addition, it is substantially equivalent to the identified predicate for all relevant parameters (e.g. intended use, target population, materials, etc.).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2001

Mr. Peter C. Aprile, R.Ph.
Senior Director, Regulatory
and Quality Affairs
Nastech Pharmaceutical Company, Inc.
45 Adams Avenue
Hauppauge, New York 11788

Re: K012088
Trade/Device Name: Mammary Aspiration Specimen Cytology Test
Regulation Number: 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: October 10, 2001
Received: October 18, 2001

Dear Mr. Aprile:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012088

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K012088

Device Name: Mammary Aspiration Specimen Cytology Test (MASCT)

Indications For Use: The MASCT device is intended for use in the collection of nipple aspirate fluid for laboratory cytological testing.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012088